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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/073,138	05/05/98	KAWAKAMI Y	2026-4124US3

HM21/1103

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EXAMINER	
HUFF, S	

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 11/03/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary

Application No.	Applicant(s)
09/073,138	Kawakami et al
Examiner	**Group Art Unit**
Sheela J. Huff	1642

☒ Responsive to communication(s) filed on *Sep 4, 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *29-31* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *29-31* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply w/ Seq. Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-28 and 32-38 were cancelled in the transmittal filed on 5/5/98. The Examiner did not see this and sent out the restriction requirement, mailed 7/1/98. This restriction requirement is withdrawn in view of the fact that cancelled claims had been included in the restriction. Claims 29-31 are pending and currently under consideration.

Sequence Listing

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is directed to MPEP 2422.05 for procedures for filing sequence listing in continuations.

Information Disclosure Statement

3. The IDS filed 5/5/98 has been considered and an initialed copy of the PTO-1449 is enclosed.

Claim Rejections - 35 USC § 112

4. Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of gp100 and several gp100 peptides (SEQ ID No. 33, 46-49, 34 and 40--see page 96 of specification) to induce tumor regression, does not reasonably provide enablement for peptides having any contiguous amino acid composition therein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's claims read on the use of peptides as small as dipeptides and peptides are large as 660 amino acids to treat melanomas. The examples given in the specification are limited to short peptides consisting of about 10-12 amino acids. Thus, it is clear from applicant's own specification that there are limitations as to what the contiguous sequence of amino acids can be. Inserting these limitations into the specification will overcome this rejection. Absent this limitations, the claims read on thousands and thousands of peptides (peptides ranging in size from dipeptides to peptides having 660 amino acids). Applicant has not demonstrated that any peptides smaller than 10 amino acids or greater than 12 amino acids can have the claimed effect. It is well known in the art of peptide chemistry that altering the size of the peptide leads to changes in conformation, overall polarity, steric hinderance and charge. This would alter the peptides' ability to interact with its appropriate counterpart

and this would clearly disrupt the interaction and thus effect of the peptide. There is no guidance in the specification as to how long or how short the peptide must be in order for the peptide to retain its ability. Thus, undue experimentation would be required by one skilled in the art to determine which of the thousands of peptides possess the ability recited in the claims.

5. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "effective amount" renders the claim vague and indefinite. Effective for what???

Conclusion

6. The claims are free from the art of record because the prior art neither teaches nor suggests full length gp100 or fragments thereof in a pharmaceutical formulation with a pharmaceutically acceptable carrier.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday, Wednesday and Friday from 6:30am to 4:00pm and Tuesday 1:00pm to 5:00pm.

If attempts to teach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached on (703)308-4310.

The FAX phone number for the group is (703)308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**paula.hutzell@uspto.gov**].

All Internet e-mail communications will be made of record in the application file.

PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff
October 26, 1998

Sheela J. Huff
Primary Examiner

Application No.: 09/073138

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☑ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE